INTERNATIONAL STANDARD

ISO 5356-1

Fourth edition
2015-03-15

Anaesthetic and respiratory equipment — Conical connectors —

Part 1:
Cones and sockets

Matériel d'anesthésie et de réanimation respiratoire — Raccords coniques —

Partie 1: Raccords mâles et femelles

Reference number
ISO 5356-1:2015(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This fourth edition cancels and replaces the third edition (ISO 5356-1:2004), which has been technically revised with the following changes:

— harmonizing the terminology used in the text with the title of this part of ISO 5356;

— deleting the definition of 22 mm latching connector because the content is covered by the text of this part of ISO 5356;

— including 11,5 mm cones and sockets;

— adding the minimum internal diameter for the 30 mm cone and changing the minimum internal diameter of the 8,5 mm cone from 6,0 mm to 6,25 mm;

— deleting the requirements on reuse of 22 mm latching sockets and cones because this is covered by the standards for the specific medical devices and accessories;

— making the recess and the shoulder for the 22 mm cone conditional;

— correcting the dimension *D* for the plug and ring test gauges for 8,5 mm cones and sockets made of materials other than metal in Annex A of this part of ISO 5356;

— restructuring the document for clarity.

ISO 5356 consists of the following parts, under the general title *Anaesthetic and respiratory equipment — Conical connectors*:

— *Part 1: Cones and sockets*

— *Part 2: Screw-threaded weight-bearing connectors*

Introduction

In clinical practice, several breathing attachments used in anaesthetic and respiratory equipment may have to be joined together to provide a suitable breathing system. Items of medical equipment, such as a humidifier or a spirometer, are often incorporated into the breathing system which might also be connected to an anaesthetic gas scavenging system. Connections for these purposes are usually cone and socket joints, and a lack of standardization of these connections has given rise to problems of interchangeability when connecting equipment made by different manufacturers. This part of ISO 5356 specifies the requirements and dimensions for cones and sockets used in anaesthetic and respiratory equipment.

An important consideration is that conical connections need to be secure but nevertheless disconnectable by the operator. The use of cones and sockets meeting the requirements of this part of ISO 5356 will not necessarily prevent them being disconnected accidentally. To minimize the risk of 22 mm connectors being accidentally disconnected, latching sockets can be used.

Annex A includes a figure and a table detailing plug and ring test gauges that are used to check cones and sockets made of materials other than metal. Annex B, Annex C, and Annex D provide test methods for latching sockets, Annex E includes a figure and table detailing plug and ring test gauges that can be used to check metal cones and sockets, and Annex F contains recommendations for testing the security of latching sockets.

Figure 1, detailing the dimensions and tolerances of cones and sockets, has been prepared in accordance with ISO 3040.

In this document, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— test methods: *italic type.*

Anaesthetic and respiratory equipment — Conical connectors —

Part 1: Cones and sockets

1 Scope

This part of ISO 5356 specifies dimensional and gauging requirements for cones and sockets intended for connecting anaesthetic and respiratory equipment, e.g. in breathing systems, anaesthetic gas scavenging systems, and vaporizers. The cones and sockets are therefore not regarded as devices in their own right.

This part of ISO 5356 gives requirements for the following cones and sockets:

— 8,5 mm and 11,5 mm sizes intended for use in neonatal and paediatric breathing systems;

— 15 mm and 22 mm sizes intended for general use in breathing systems;

— 22 mm latching sockets (including performance requirements);

— 23 mm size intended for use with vaporizers, but not for use in breathing systems;

— 30 mm size intended for the connection of a breathing system to an anaesthetic gas scavenging system.

This part of ISO 5356 does not specify the medical devices and accessories on which these cones and sockets are to be provided.

Requirements for the application of cones and sockets are not included in this part of ISO 5356, but are or will be given in the relevant International Standards for specific medical devices and accessories.

NOTE Requirements for screw-threaded weight-bearing connectors are specified in ISO 5356-2.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

3 Dimensional requirements

3.1 General requirements

3.1.1 Cones and sockets made of metal shall comply with Figure 1 and the dimensions given in Table 1 as appropriate.

Check compliance by functional testing.

NOTE Annex E includes a figure and table detailing plug and ring test gauges that can be used to check metal cones and sockets.

3.1.2 Cones and sockets made of non-metallic materials shall comply with Figure 1 and the dimensions given in Table 1 except that the dimensions *A* and *B* and ratio *F* may vary from those given in Table 1.

Check compliance by engaging the cone or socket in the appropriate plug or ring test gauge according to Figure A.1 and Table A.1, by applying an axial force of (35 ± 3,5) N for 8,5 mm, 11,5 mm, and 15 mm cones or sockets and (50 ± 5) N for 22 mm and 30 mm cones or sockets while simultaneously rotating the cone or socket (20 ± 5)°. Its leading edge shall lie between the minimum and maximum diameter steps of the gauge. The cones or sockets and gauges shall be maintained at a temperature of (20 ± 3) °C during the test.

NOTE Because cones or sockets made from plastics materials (for example polyamide, polyacetal, polycarbonate, polysulfone) can vary greatly in their physical characteristics, it is not considered practicable to specify dimensions *A*, *B*, and ratio *F*; for this reason, gauging requirements have been included. It is also considered impracticable to generalize on matters such as cold flow and thermal instability, as well as possible changes in physical characteristics, contact with solvents, etc.

a For the 8,5 mm cone and the 30 mm cone, dimension *G* over the minimum length, *H*, as specified in Table 1.

NOTE The radius on the entrance to the socket and on the leading edge of the cone is not intended to be less than 0,5 mm and not more than 0,8 mm.

Figure 1 — Interconnecting details of cones and sockets

Table 1 — Dimensions of cones and sockets (see Figure 1)

Dimensions in millimetres

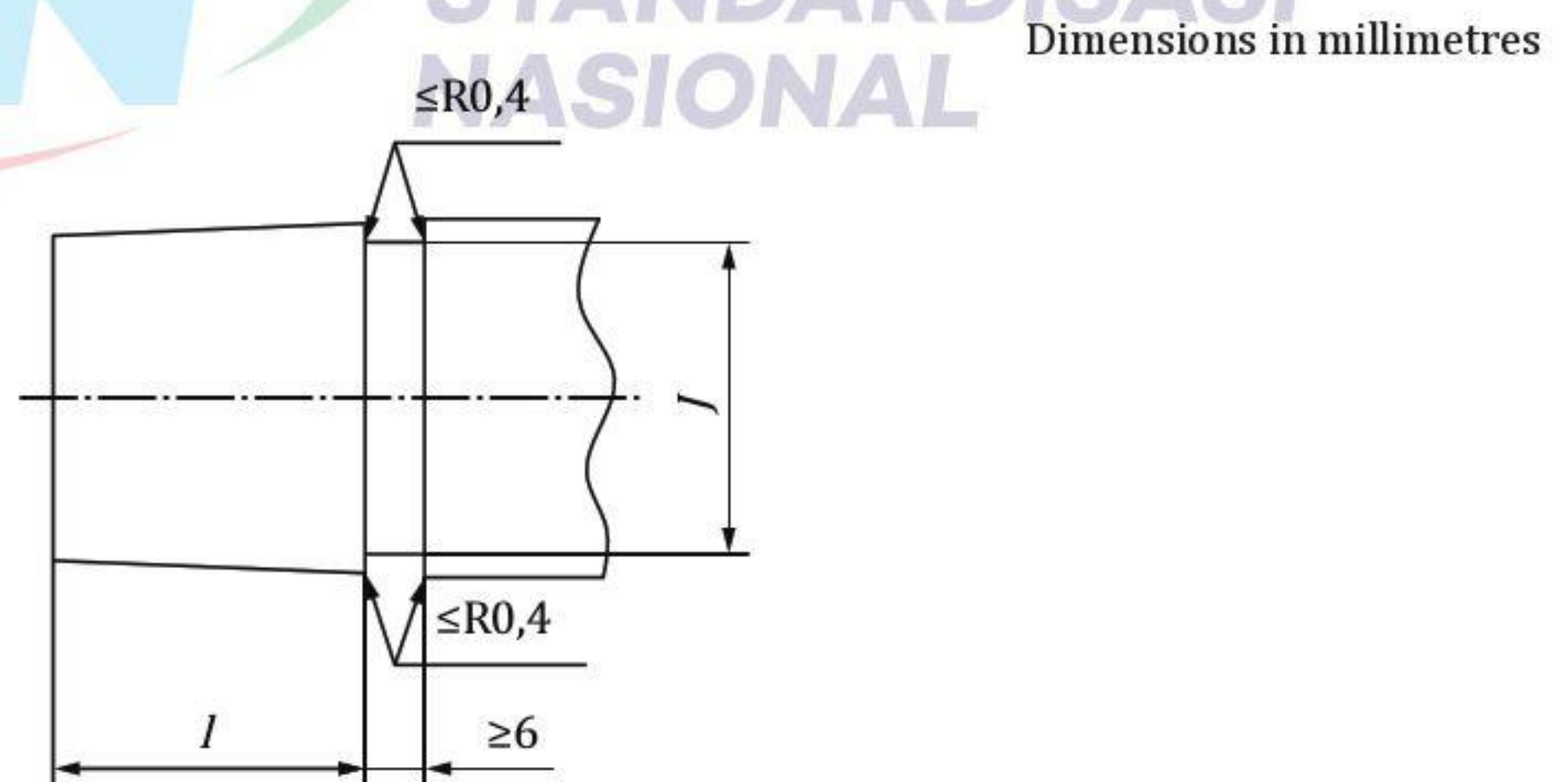
Connector size			Taper length	Clearance to shoulder (if present)	Length to taper	Taper ratio	Minimum internal diameter of cone	Minimum length of internal diameter of the cone *(G)*
	A	*B*	*C*	*D*	*E*	*F*	*G*	*H*
8,5	8,45 ± 0,04	6	≥6,4	≥8,9	≥8	1:19	6,25	6,0
11,5	11,50 ± 0,04	10	≥13,5	≥16	≥15	1:40	a	a
15	15,47 ± 0,04	10	≥16	≥16	≥14,5	1:40	a	a
22	22,37 ± 0,04	15	≥21	See Figure 3	See Figure 3	1:40	a	a
23	23,175 ± 0,02	13	≥18	≥18	≥15	1:36	a	a
30	30,9 ± 0,05	14	≥18	≥18	≥14	1:20	27,0	12,0

a Not specified.

3.2 Additional requirements

3.2.1 22 mm cones designed to connect to a breathing tube complying with ISO 5367:2014, 5.3.2.2, or a latching socket (see Clause 4) shall incorporate a recess, the dimensions of which are given in Figure 2.

Check compliance by functional testing.

Dimensions in millimetres

Key

l taper length: $19{,}5_{0}^{+0{,}5}$

J diameter of recess: $20_{0}^{+0{,}5}$

Figure 2 — Details of recess for 22 mm cones

3.2.2 22 mm cones, designed to connect to a face mask shall incorporate a means to prevent over insertion (e.g. shoulder) and comply with the dimensions given in Figure 3.

Check compliance by functional testing.

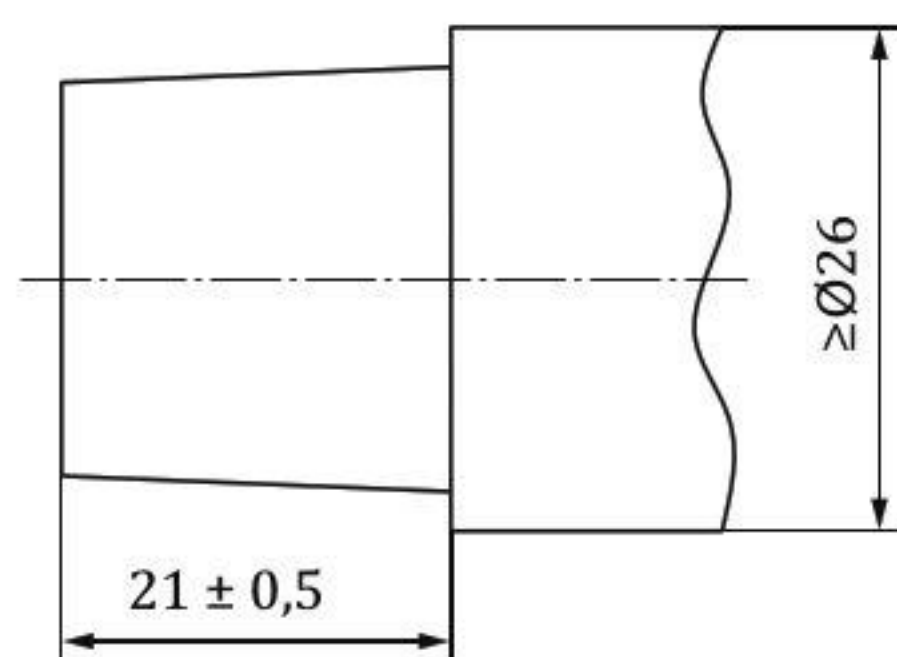



Figure 3 — Dimensions of 22 mm cones designed to connect to a face mask

4 22 mm latching sockets

4.1 22 mm latching sockets shall be designed to engage with the recess of the 22 mm cone as specified in Figure 2.

Check compliance by visual inspection.

4.2 Engaged latching cones and sockets shall not become disconnected when subjected to an axial separation force of (50 ± 5) N for 10 s.

Check compliance by the test method given in Annex B.

4.3 Engaged latching cones and sockets shall not leak by more than 5 ml/min (corrected to 20 °C and 101,3 kPa) when subjected to an internal pressure of (8 ± 0,5) kPa.

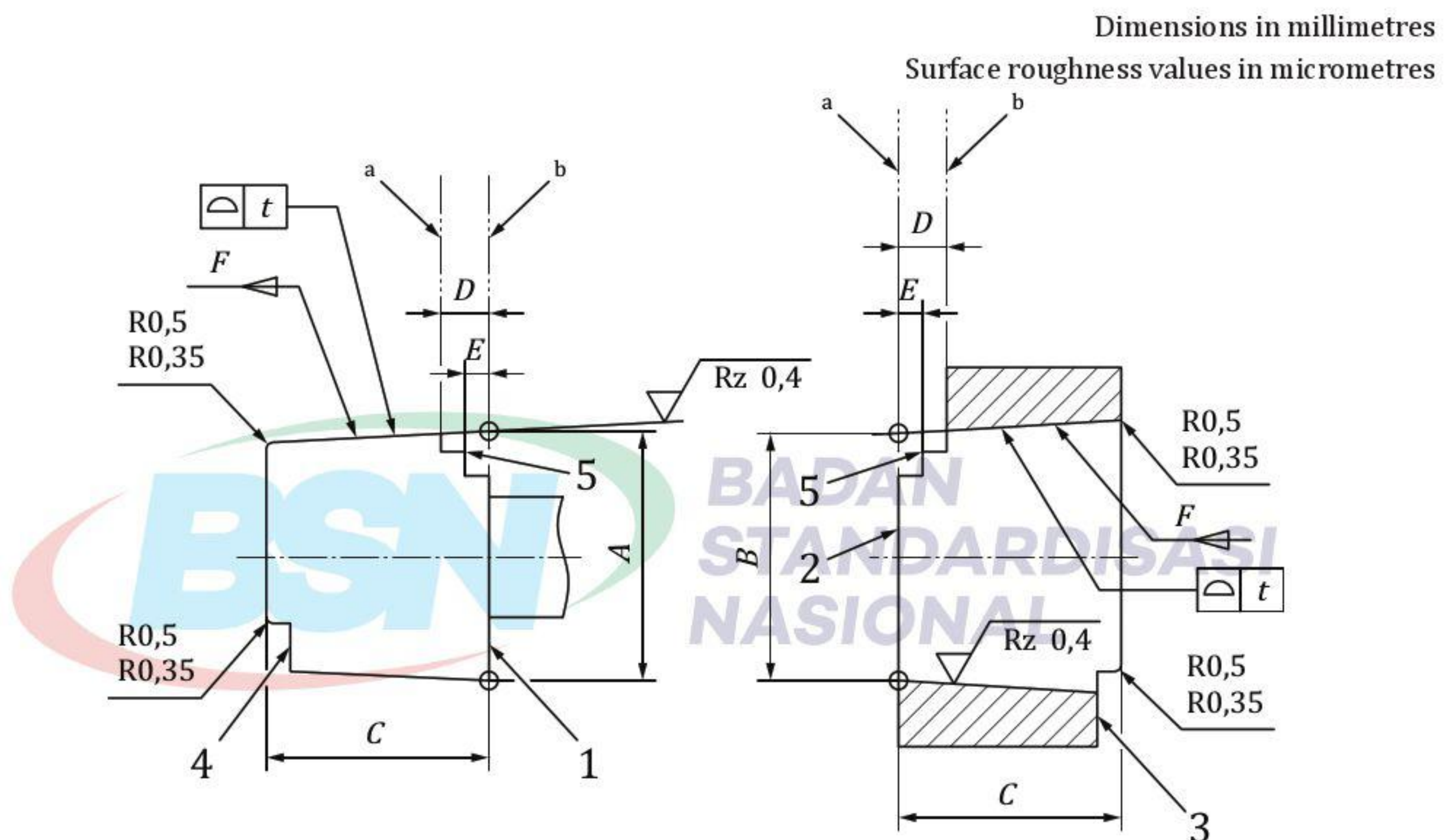
Check compliance by the test method given in Annex C.

4.4 Engaged latching cones and sockets shall meet the requirements of 4.2 and 4.3 after being dropped from a height of 1 m.

Check compliance by the test method given in Annex D.

Annex A
(normative)

Plug and ring test gauges for cones and sockets made of materials other than metal

Figure A.1 and Table A.1 give details of plug and ring gauges for use in checking cones and sockets made of materials other than metals.

Dimensions in millimetres

Surface roughness values in micrometres

Key

1 face A

2 face B

3 step to check mating gauges ground flush to face A

4 step to check mating gauges ground flush to face B

5 basic steps

a Position min.

b Position max.

NOTE 1 Basic and mating gauge steps are optional.

NOTE 2 Test gauges are usually made of metal.

Figure A.1 — Plug and ring test gauges for cones and sockets made of materials other than metal

Table A.1 — Plug and ring test gauges for cones and sockets made of materials other than metal — Dimensions (see Figure A.1)

Dimensions in millimetres

Connector size	*A*	*B*	*C*	*D*	*E*	*F*	Tolerance on taper per unit of length on diameter
8,5	8,50 ± 0,005	8,09 ± 0,005	8,4 ± 0,005	1,91 ± 0,005	See NOTE	1:19	0,053 ± 0,000 2
11,5	11,525 ± 0,005	11,165 ± 0,005	15,5 ± 0,005	4,3 ± 0,005	2,2 ± 0,005	1:40	0,025 ± 0,000 2
15	15,525 ± 0,005	15,165 ± 0,005	14,5 ± 0,005	4,3 ± 0,005	2,2 ± 0,005	1:40	0,025 ± 0,000 2
22	22,425 ± 0,005	21,94 ± 0,005	19,5 ± 0,005	5,2 ± 0,005	2,2 ± 0,005	1:40	0,025 ± 0,000 2
30	30,98 ± 0,005	30,12 ± 0,005	17,2 ± 0,005	3,1 ± 0,005	1,6 ± 0,005	1:20	0,050 ± 0,000 2

NOTE Gauges for 8,5 mm cones and sockets have only one mating step.

Annex B
(normative)

Test for security of engagement of 22 mm latching sockets to cones

B.1 Condition a cone complying with Figure 2 and the latching socket for 1 h at a temperature of (35 ± 3) °C and relative humidity of at least 80 %, and carry out the test under the same conditions.

B.2 Engage the 22 mm latching socket with the cone in accordance with the manufacturer's instructions.

B.3 After 1 min of engagement without activation of any disengagement mechanism, apply for 10 s an axial separation force of (50 ± 5) N and, unless the 22 mm latching socket permits free radial rotation, also apply a torque of (25 ± 5) N·cm at a rate not exceeding 20 N·s^{-1}.

B.4 Observe whether the assembled latching socket and the cone become disconnected.

NOTE Examples of suitable apparatus that can be used to test the security of engagement, together with a more detailed test procedure, are given for information in Annex F.

Annex C
(normative)

Test for leakage from 22 mm latching sockets

C.1 Take the engaged cone and 22 mm latching socket that have been tested as described in Annex B and condition them at (35 ± 3) °C.

C.2 Using air, apply an internal static pressure of (8 ± 0,5) kPa above ambient to the assembly and determine the leakage rate from the assembly, e.g. by pressure drop or volumetric method.

Annex D
(normative)

Drop procedure for 22 mm latching sockets

D.1 Condition a cone complying with Figure 2 and the 22 mm latching socket for 1 h at a temperature of (20 ± 3) °C and relative humidity of at least 80 %, and carry out the test under the same conditions.

D.2 Engage the 22 mm latching socket with the cone in accordance with the manufacturer's instructions. Attach the cone to a breathing tube complying with ISO 5367 and having a length of 2 m.

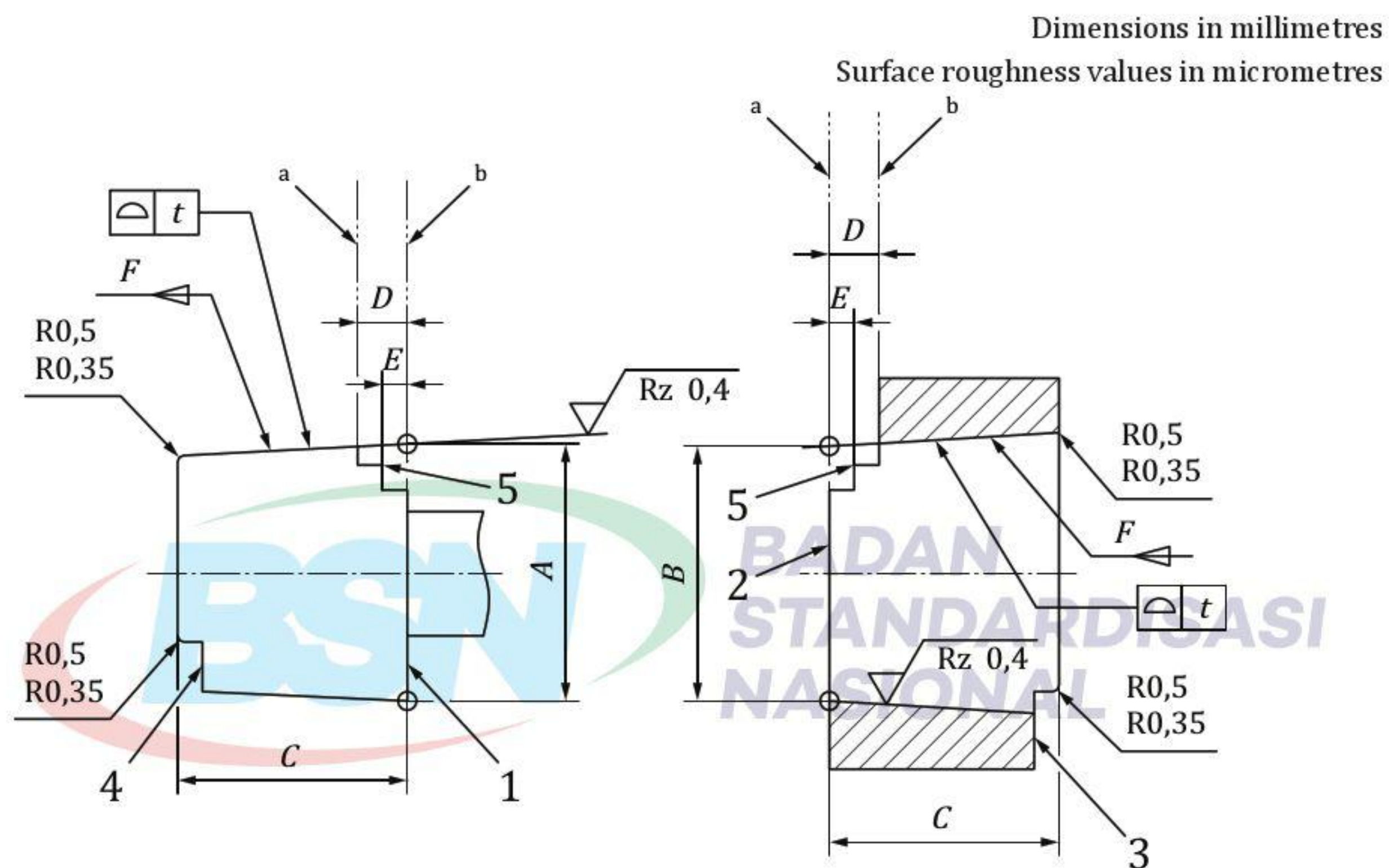
D.3 Attach the opposite end of the breathing tube to a point 1 m above a 50 mm thick hardwood board (e.g., hardwood having a density greater than 700 kg/m^3) standing on a rigid base (e.g. a concrete block).

D.4 Raise the engaged 22 latching socket and cone to a point 1 m above the board and 2 m distant from the other end of the breathing tube and release them so that they fall onto the hardwood board. Repeat this five times.

D.5 Proceed with desired test.

Annex E
(informative)

Plug and ring test gauges for cones and sockets made of metal

Figure E.1 and Table E.1 give, for information, details of plug and ring test gauges that can be used to check metal cones and sockets.

Dimensions in millimetres

Surface roughness values in micrometres

Key

1 face A

2 face B

3 step to check mating gauges ground flush to face A

4 step to check mating gauges ground flush to face B

5 basic steps

a Position min.

b Position max.

NOTE Basic and mating gauge steps are optional.

Figure E.1 — Plug and ring test gauges for cones and sockets made of metal

Table E.1 — Plug and ring test gauges for cones and sockets made of metal — Dimensions
(see Figure E.1)

Dimensions in millimetres

Connector size	*A*	*B*	*C*	*D*	*E*	Taper ratio *F*	Tolerance on taper per unit of length on diameter
8,5	8,49 ± 0,005	8,094 ± 0,005	8,4 ± 0,005	1,52 ± 0,005	See NOTE	1:19	0,053 ± 0,000 2
11,5	11,51 ± 0,005	11,18 ± 0,005	15,5 ± 0,005	3 ± 0,005	1,6 ± 0,005	1:40	0,025 ± 0,000 2
15	15,51 ± 0,005	15,18 ± 0,005	14,5 ± 0,005	3 ± 0,005	1,6 ± 0,005	1:40	0,025 ± 0,000 2
22	22,41 ± 0,005	21,955 ± 0,005	19,5 ± 0,005	3 ± 0,005	1,6 ± 0,005	1:40	0,025 ± 0,000 2
23	23,195 ± 0,003	22,794 ± 0,003	16 ± 0,005	1,33 ± 0,005	0,72 ± 0,005	1:36	0,0278 ± 0,000 2
30	30,95 ± 0,005	30,15 ± 0,005	17 ± 0,005	1,9 ± 0,005	1 ± 0,005	1:20	0,050 ± 0,000 2

NOTE Gauges for 8,5 mm connector have only one mating step.

Annex F
(informative)

Suggested apparatus and methods for testing the security of engagement of 22 mm latching sockets

F.1 Method 1 — Bench-mounted test equipment

F.1.1 Apparatus

A typical bench-mounted apparatus for testing the security of engagement of 22 mm latching sockets is shown in Figure F.1. The test cone should be a 22 mm cone dimensioned as shown in Figure 2 but with all the tolerances reduced to ±0,005 mm and a surface finish of 0,4 µm.

NOTE There are a number of methods for applying the test forces, and Figure F.1 is illustrative of only one approach. Other methods include the use of gravity loading by weights or liquid containers.

The essential features of the apparatus should ensure that the tensile force can be applied in a truly axial direction and that torque can be applied without changing the tensile force. To minimize the effects of friction of the apparatus, the tensile force should be measured directly between the 22 mm latching socket and the test cone.

F.1.2 Procedure

F.1.2.1 Secure the 22 mm latching socket to be tested in the self-centring holder of the apparatus (F.1.1), ensuring that the method of securing the 22 mm latching socket does not deform the section or sections that are intended to engage with the test cone.

F.1.2.2 Condition the 22 mm latching socket and the apparatus at a temperature of (35 ± 3) °C and a relative humidity of at least 80 % for 1 h.

If a number of 22 mm latching sockets are to be tested, some can be conditioned at the required temperature and relative humidity without being secured to the apparatus, provided that they are conditioned again for at least 5 min after being secured to the apparatus.

F.1.2.3 Engage the 22 mm latching sockets with the test cone in accordance with the manufacturer's instructions.

F.1.2.4 After 1 min, attach the force-measuring device and apply an axial separation force at a rate not exceeding 20 $N \cdot s^{-1}$ until a force of (50 ± 5) N is being applied. Maintain this force for 10 s without activating any disengagement mechanism, and observe whether the engaged 22 mm latching socket and test cone become disconnected.

F.1.2.5 Without reducing the tensile load and without activation of any disengagement mechanism, apply a torque of (25 ± 5) N·cm or rotate the test cone through an angle of 20°, whichever occurs first. Maintain this torque or position for 10 s and observe whether the engaged 22 mm latching socket and test cone become disconnected.

F.2 Method 2 — Handheld test equipment

F.2.1 Apparatus

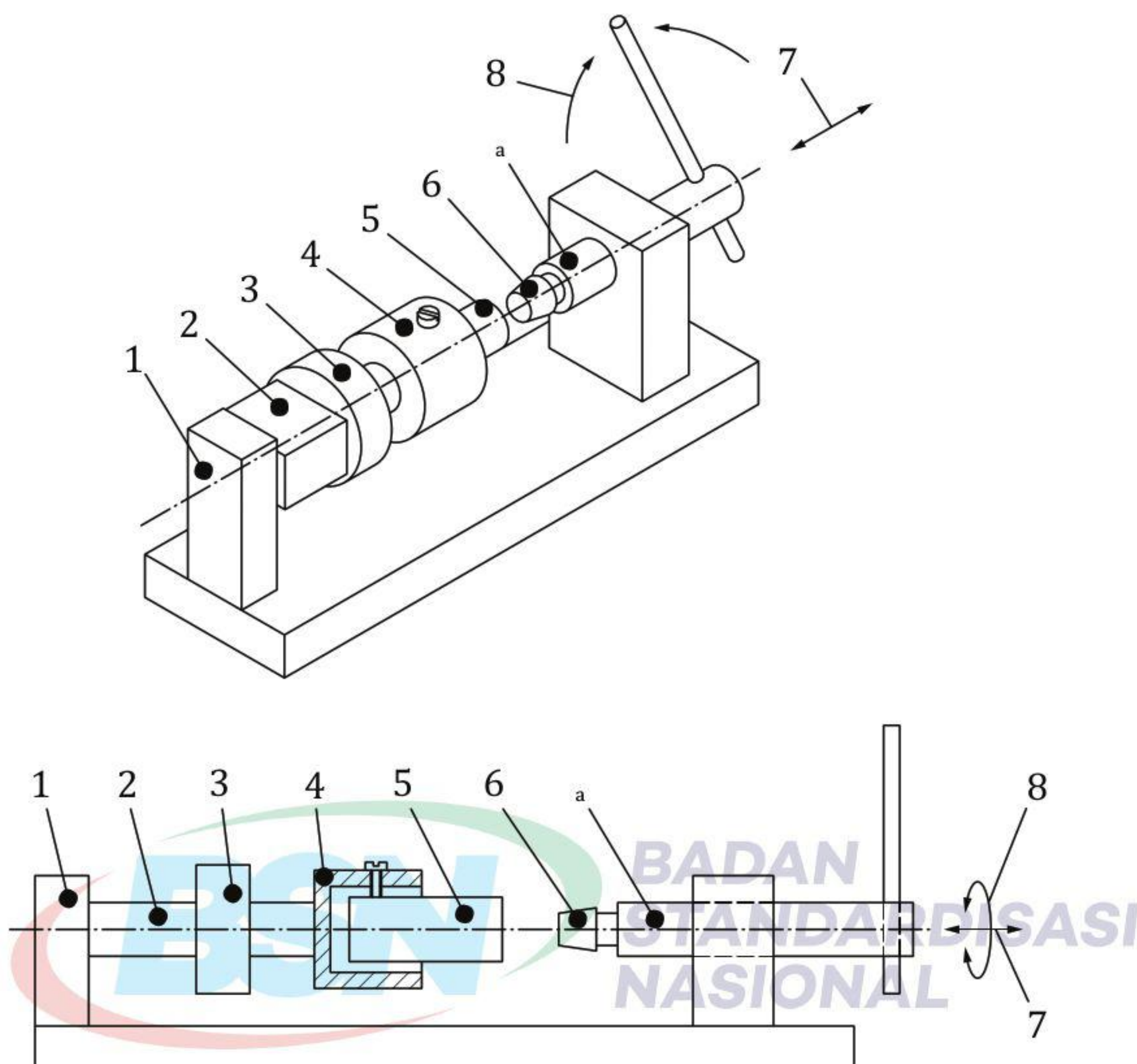
A typical handheld apparatus for testing the security of engagement of 22 mm latching sockets is shown in Figure F.2.

F.2.2 Procedure

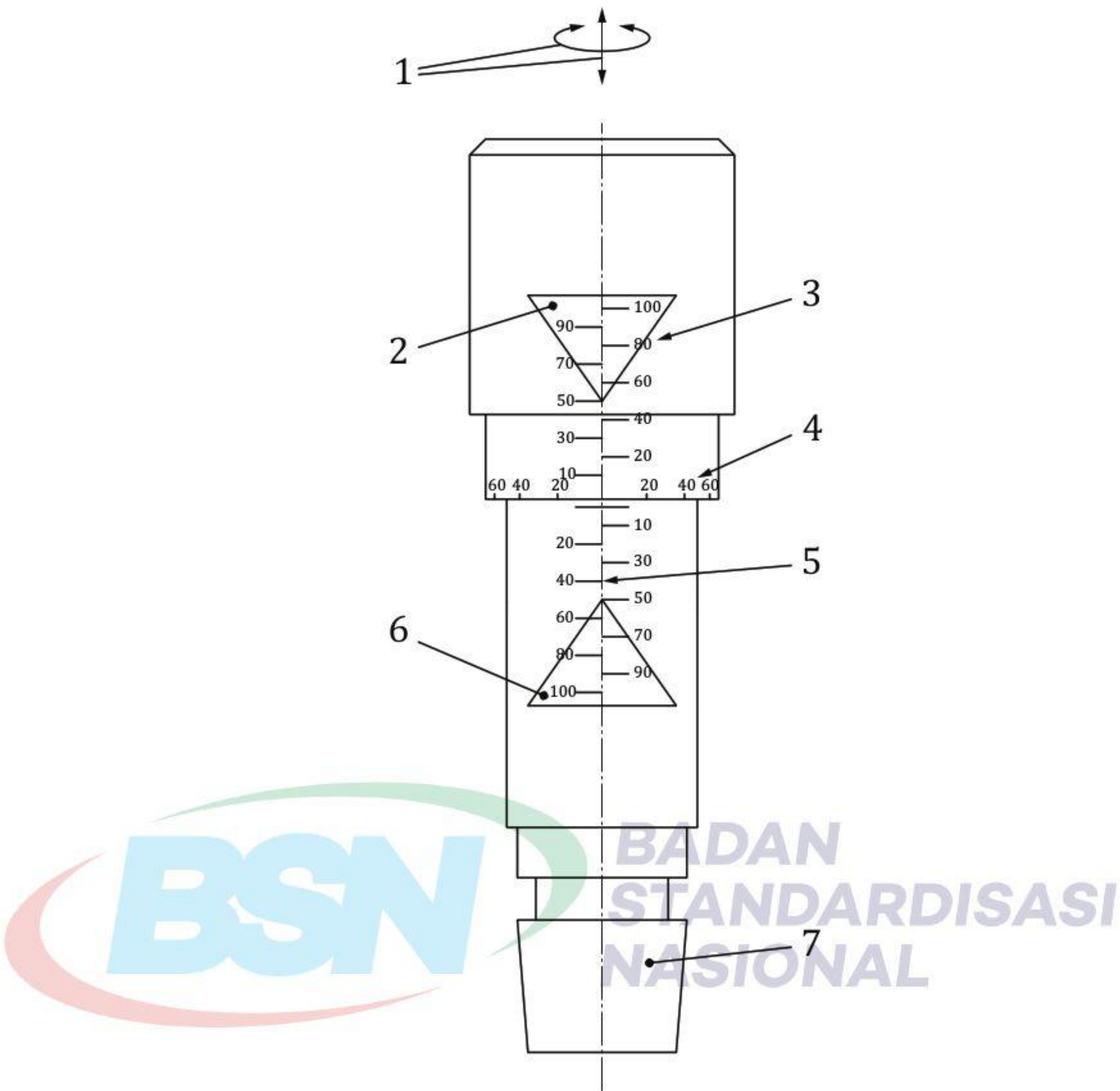
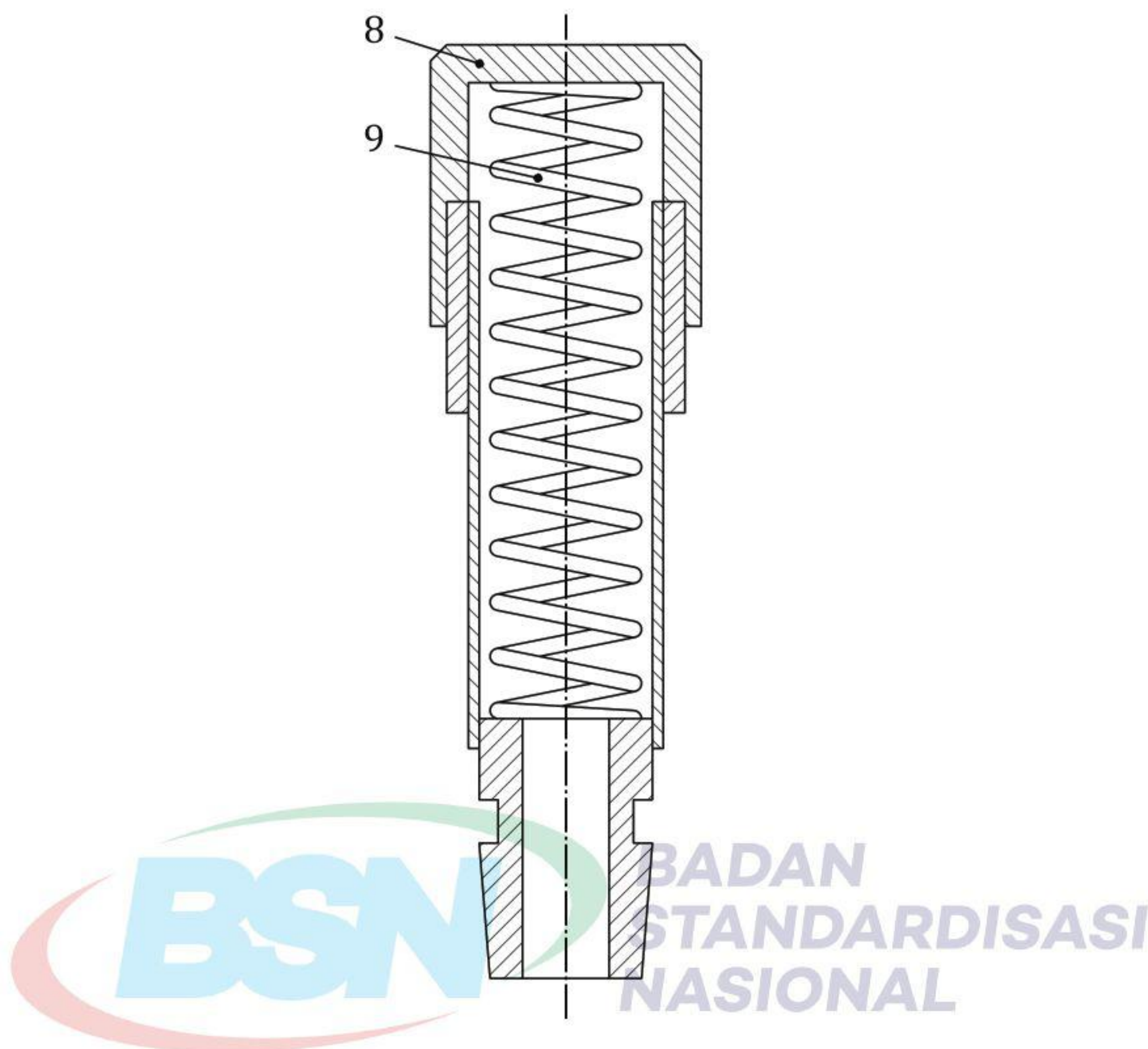
F.2.2.1 Condition the 22 mm latching socket and the apparatus (F.2.1) at a temperature of (35 ± 3) °C and a relative humidity of at least 80 % for 1 h.

F.2.2.2 Engage the 22 mm latching socket with the test cone on the apparatus.

F.2.2.3 After 1 min, manually apply an axial separation force at a rate not exceeding 20 N·s^{-1} until a force of (50 ± 5) N is applied. Maintain this force for 10 s without activation of any disengagement mechanism, and observe whether the engaged 22 mm latching socket and test cone become disconnected.

F.2.2.4 Without reducing the tensile load and without activation of any disengagement mechanism, apply a torque of (25 ± 5) N·cm or rotate the test cone through an angle of 20°, whichever occurs first. Maintain this torque or position for 10 s, and observe whether the engaged 22 mm latching socket and test cone become disconnected.

Key

1 rigid support
2 axial load meter
3 torque meter
4 holder
5 22 mm latching socket under test
6 22 mm test cone
7 application of adjustable axial force
8 application of adjustable torque
a Free to slide and rotate.

Figure F.1 — Apparatus for testing the security of engagement of 22 mm latching sockets (Method 1 — Bench-mounted)

a) External view

b) Sectional view

Key

1 application of torque or push or pull by hand
2 area of scale indicating acceptable pull and twist forces
3 pull-force scale
4 torque scale
5 push-force scale
6 area of scale indicating acceptable push and twist forces
7 22 mm test cone
8 knob
9 coil spring fixed at both ends

Torque and force scales should be precalibrated using the apparatus in Figure F.1.

Figure F.2 — Apparatus for testing the security of engagement of 22 mm latching sockets (Method 2 — Handheld)

Bibliography

[1] ISO 3040:2009, *Geometrical product specifications (GPS) — Dimensioning and tolerancing — Cones*

[2] ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

[3] ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*